#### (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

# (19) World Intellectual Property Organization International Bureau





# (10) International Publication Number WO 2010/072664 A1

#### (43) International Publication Date 1 July 2010 (01.07.2010)

- (51) International Patent Classification: A61M 25/02 (2006.01) A61M 5/158 (2006.01)
- (21) International Application Number:

PCT/EP2009/067490

(22) International Filing Date:

18 December 2009 (18.12.2009)

(25) Filing Language:

English

(26) Publication Language:

English

- (30) Priority Data:

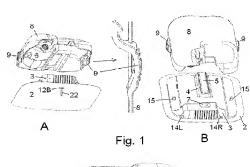
  PA 2008 01833 22 December 2008 (22.12.2008) DK
  61/139,833 22 December 2008 (22.12.2008) US
- (71) Applicant (for all designated States except US): UN-OMEDICAL A/S [DK/DK]; Birkerød Kongevej 2, DK-3460 Birkerød (DK).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): HØRDUM, Elo, Lau [DK/DK]; Stenhavevej 14E, DK-2970 Hørsholm (DK).
- (74) Agent: NILAUSEN, Kim; Zacco Denmark A/S, Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).

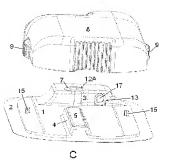
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Published:

- with international search report (Art. 21(3))

#### (54) Title: MEDICAL DEVICE COMPRISING ADHESIVE PAD





(57) Abstract: The invention relates to an adhesive pad and a surface plate which in combination can provide a medical device which is to be placed on the skin of a patient. The combined medical device is provided with a subcutaneous part which necessitates that the device is securely and comfortably attached to the patient's skin. Often such devices are used to transfer medication such as insulin to a patient from a reservoir. An embodiment according to the invention relates to a medical device comprising - a cannula (22) or another part to be positioned subcutaneously when in use, a surface plate (1) provided with a contact surface and with an opening (12B) through which the cannula (22) or another subcutaneously positioned part passes when the medical device is in use, and - an adhesive pad (2) secured to the contact surface of the surface plate (1) providing adhesion of the surface plate (1) to a skin surface which adhesive pad (2) comprises - a first surface facing the contact surface and having areas unreleasably secured to the contact surface by welding, and - a second surface facing the skin of a patient during use and having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient wherein an adhesive part (30) has been placed between the contact surface of the surface plate (1) and the first surface of the adhesive pad (2) in an area where the two surfaces have not been welded together thereby securing these unwelded areas of the contact surface to the first surface.

### Medical device comprising adhesive pad

#### The technical field

The invention relates to an adhesive pad and a surface plate which in combination can provide a medical device which is to be placed on the skin of a patient. The combined medical device is provided with a subcutaneous part which necessitates that the device is securely and comfortably attached to the patient's skin. Often such devices are used to transfer medication such as insulin to a patient from a reservoir.

#### 10 Prior art

Traditionally adhesive pads are secured to a medical device such as an infusion set by welding. Welding is highly efficient and it would not be possible to remove the adhesive pad from the medical device after the adhesive pad has been welded on to the medical device without destroying at least the adhesive pad.

15

20

25

30

35

5

WO 2006/061354 relates to a medical device comprising a transcutaneous device unit and a process unit. The transcutaneous device unit is adapted to be mounted to a skin surface of a subject and comprises a first housing, a transcutaneous device, and may comprise a flexible patch portion with an upper surface and a lower mounting surface adapted for application to the skin of a subject. The process unit comprises a second housing with a lower surface and a process assembly. The first and second housings are adapted to be secured to each other in such a way that the lower surface of the second housing is allowed to move freely relative to at least a portion of the underlying skin surface or patch. In this way a relatively flexible patch portion can adapt to the skin surface to which it is mounted both statically and dynamically without being restricted in its movements by the normally much stiffer process unit. The flexible patch portion comprise a flexible sheet (12) and a flexible support plate (11) extending from the housing, the support plate further comprises a flexible reidge formed support member (13) extending from the housing. The support plate (11) as well as the housing may be fully or partly attached to the flexible sheet e.g. by welding or adhesives.

It is though a problem that welding destroys the ability to adhere on the adhesive surface of the adhesive pad, i.e. the surface which is facing the skin of the patient after having mounted the medical device, in those areas where welding has taken place. Therefore welding is a balance between welding areas enough to secure the WO 2010/072664 PCT/EP2009/067490 2

adhesive pad adequately to the medical device and leaving an adhesive area large enough to allow the adhesive pad to adhere adequately to the patient. The adhesive pad is considered to adhere adequately when the medical device is kept in place without moving; especially should any subcutaneously inserted parts such as cannulas or sensors be kept completely stationary until the user decides to remove the device.

One way to solve this problem is to increase the general area of the adhesive pad i.e. use an adhesive pad which is considerably larger than the surface of the medical device facing the adhesive pad. However, this approach is most convenient for smaller medical devices as the patients do not appreciate having large adhesive pads removed from their skin.

#### The invention

5

10

15

20

25

30

35

The object of the invention is to provide a medical device comprising a cannula (22) or another part to be positioned subcutaneously when in use, a surface plate (1) provided with a contact surface and with an opening (12B) through which the cannula (22) or another subcutaneously positioned part passes when the medical device is in use, and an adhesive pad (2) secured to the contact surface of the surface plate (1) providing adhesion of the surface plate (1) to a skin surface which adhesive pad (2) comprises a first surface facing the contact surface and having areas unreleasably secured to the contact surface by welding, and a second surface facing the skin of a patient during use and having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient. The medical device further comprises an adhesive part (30) which has been placed between the contact surface of the surface plate (1) and the first surface of the adhesive pad (2) in an area where the two surfaces have not been welded together thereby securing these unwelded areas of the contact surface to the first surface.

One advantage of this inventive medical device is that it is possible to have an adhesive pad which fits e.g. an arm or another skin surface having a certain rounding perfectly, and at the same time having a relatively large rigid surface plate attached securely to the adhesive pad. This means that the patient carrying the device has an increased freedom in relation to where to position the device as the patient or the user of the device does not have to

take the form of the skin surface into account when positioning the device but instead the patient can have the medical device positioned at a place where it is conveniently hidden by the clothese or conveniently positioned for other reasons.

5

The at least one adhesive part (30) further assures that the surface plate (1) and especially the subcutaneous part is kept in its desired subcutaneous position although parts of the surface plate are somehow distanced from the adhesive pad (2).

10

15

20

25

30

35

According to one embodiment the adhesive part (30) comprises a piece of double adhesive material i.e. each side of the adhesive part (30) is provided with adhesive coating or the adhesive part (30) comprises a coating of adhesive placed directly on the contact surface of the surface plate (1) or the adhesive part (30) comprises a coating of adhesive placed directly on the first surface of the adhesive pad (2).

According to a further embodiment an adhesive part (30) is positioned along the edge of the opening (12B) of the contact surface of the surface plate (1) through which opening (12B) the cannula (22) or another subcutaneously positioned part passes. According to this embodiment the portion of the surface plate (1) surrounding the subcutaneously positioned part is kept stationary relative to the adhesive pad and as the adhesive pad has its full adhesive strength in this area; this portion of the adhesive pad is kept stationary relative to the patient's skin. This prevents trauma of the patient's skin and increase the comfort for the patient.

According to a further embodiment the adhesive part (30) comprises a piece of double adhesive tape which can be sterilized by either gamma radiation or ethylene oxide gas.

According to a further embodiment the area covered by the adhesive part (30) is between  $0.5 - 1.5 \text{ cm}^2$ . Normally the area covered by the adhesive part (30) is around  $1 \text{ cm}^2$  but the exact area depend on both the form of the adhesive part (30) and of the size of the surface plate (1) and the adhesive pad (2).

According to a further embodiment each separate welding is provided in the form of a spot welding placed on at least two opposite sides of the adhesive part (30) in order to avoid peeling i.e. separation between the surface plate 1 and the adhesive pad 2. The spot weldings are placed relatively close to the adhesive part (30) i.e. within 10 mm from the edge of the adhesive part (30).

5

10

20

25

30

35

According to a further embodiment a welding is also placed between the adhesive part (30) and at least one edge of the surface plate 1 in order to avoid that the surface plate 1 pivots away from the adhesive pad 2 and thereby cause and inconvenience to the patient. The welding can e.g. be placed between the adhesive part (30) and at least one edge of the surface plate 1 comprising either a larger circular welding as shown in fig. 2A-2) or several spot weldings as shown in fig. 2E-2G.

According to a further embodiment the subcutaneously positioned part is a sensor e.g. the sensor can register the content of glucose in the blood of the patient.

A further object of the invention is to provide a base part comprising a surface plate (1) provided a contact surface and having an opening (12B) through which a cannula (22) or another subcutaneously positioned part passes when the medical device is in use, and an adhesive pad (2) secured to the contact surface of the surface plate (1) providing adhesion of the surface plate (1) to a skin surface which adhesive pad comprises a first surface facing the contact surface and having areas unreleasably secured to the contact surface by welding, and a second surface facing the skin of a patient during use and having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient. Further, an adhesive part (30) has been placed between the contact surface of the surface plate (1) and the first surface of the adhesive pad (2) in an area where the two surfaces has not been welded together thereby optimizing the adherence between these unwelded areas of the contact surface to the first surface. "Optimizing" means that the surface plate is thoroughly secured to the adhesive pad while at the same time the surface plate can move in relation to the adhesive pad.

PCT/EP2009/067490 WO 2010/072664

A further object of the invention is to provide an adhesive pad secured to a medical device and providing adhesion of the medical device to a skin surface which adhesive pad comprises a first surface facing the medical device having areas unreleasably secured to the medical device by welding, and a second surface having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient, and also the first surface has at least one area provided with an adhesive securing the first surface to the medical device. According to this embodiment the medical device can be provided with a cannula (22) and the at least one area provided with an adhesive is surrounding the point where the cannula pass through the adhesive pad (2).

## **Detailed description**

5

10

15

20

25

30

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1A-1C shows a prior art medical device comprising a delivery part and a base part, fig. 1A shows the device from below, fig. 1B shows the device seen from above and 1C shows the device in and end view opposite the views of fig. 1A and 1B.

Figure 2A-G show several embodiments of part of a medical device according to the invention having an approximately rectangular contact surface.

Figure 3A and B shows two embodiments of an adhesive pad to be used with a medical device provided with a cannula or another subcutaneously positioned part and having a contact surface facing a round adhesive pad, fig. 3A illustrates the prior art and fig. 3B illustrates an embodiment according to the invention.

Figs. 1A-C show an example of a medical device which device is relatively large and heavy. The device is of a type having credit card size, being rectangular and being self contained i.e. including a delivery part and without connections to other parts as the device carry both a reservoir and pumping and controlling means while in use.

35 The medical device comprises a base part which when the device is in use is secured to the skin of a patient. The base part comprises a surface plate 1

WO 2010/072664 PCT/EP2009/067490 6

and an adhesive pad 2 which adhesive pad 2 is unreleasably fastened to the surface plate 1 during manufacturing of the medical device. A connection part 3 is attached to the surface plate 1 which surface plate 1 can be constructed of a molded plastic material. The connection part 3 comprises a fluid path provided with a membrane 17 and a delivery part comprising a reservoir 6, the two parts are in a position where they are separated from each other and they are shown from different angles. In fig. 1A the two parts are shown from below. This view shows an opening 12B through which a cannula part 7 can be inserted through the base part and through which opening 12B a cannula 22 extends. The connection part 3 is provided with a cannula opening 12A which accurately fits around a cannula part 7 when the cannula part 7 is mounted in the connection part 3 i.e. the cannula opening 12A has the same shape or profile as the cannula part 7 and is just big enough to let the cannula part 7 pass through and then fit into the opening.

The surface plate 1 has a contact surface which is defined as the surface which is in contact with the proximal or the first surface of the adhesive pad 2 which is the surface of the adhesive pad 2 facing the medical device. The contact surface of the surface plate and the first side of the adhesive pad 2 has areas unreleasably secured to each other by welding. Further the second surface of the adhesive pad 2 i.e. the surface facing the skin of the patient has areas provided with a skin compatible adhesive. Normally the full surface of the second surface will be adhesive except for the areas which have been subjected to welding when joining the surface plate 1 and the adhesive pad 2 together.

In fig. 2B the cannula part 7 is shown in a position where the cannula part 7 is fully inserted. When the cannula part 7 is fully inserted, the upper surface i.e. the distal surface of the cannula part 7 is normally at level with or at a lower level than the outer surface of the connection part 3 around the cannula opening 12A. From this view it is possible to see how the reservoir 6 is positioned in the delivery part 8 and to see how two opposite positioned release handles 9 are placed at the edge of the delivery part 8. Further a longitudinal track corresponding to longitudinal raised guiding means 4 on the base part can be seen.

The two release handles 9 are formed as s-shaped bands where one end is fastened hinge-like to the housing of the delivery part 8 and the first curve in the s-shape is slightly extending the outer surface of the housing of the delivery part whereas the second curve is free i.e. not attached to the housing of the delivery part 8 and is provided with a hook-like shape which can fold around a part 15 protruding from the distal surface of the base part. When the delivery part is locked to the base part both release handles 9 are folded round a protruding part 15, when the delivery part 8 is to be removed from the base part, the two opposite release handles 9 are pushed together whereby the hook-like parts of the release handles 9 are released from the protruding parts 15 of the base part, and the delivery part can be moved backwards i.e. in the direction away from the cannula part 7 and removed from the base part in this direction.

In fig. 1B the two parts are shown from above. This view shows how the delivery part 8 of this embodiment can be joined to the base part by pushing the delivery part 8 down toward the guiding means 4 which in this case is a longitudinal raised platform having e.g. a metal lining 5 fastened to the top surface. The delivery part 8 is provided with corresponding means e.g. comprising a track corresponding to the raised platform 4. The corresponding means of the delivery part 8 can slide along the metal lining 5 of the raised platform 4 of the base part in the longitudinal direction. When the delivery part 8 arrives at its working position, the two release handles 9 engage respectively with the two protruding parts 15 protruding from the upper surface of the surface plate 1. When the delivery part 8 is in its working position it is locked in any horizontal direction by the release handles 9. The locking mechanisms make it possible to fasten and release the delivery device from the base part as often as needed i.e. a single-use base part can be combined with a multi-use delivery part.

In fig. 1C the two parts are shown from the end opposite of where the inserter was fastened before insertion of the penetrating member. From this side it is possible to see the inlet opening 13 in the connection part 3 through which e.g. medication from the reservoir 6 can enter, the inlet opening 13 is protected with a membrane to prevent contamination with microorganisms. The connection part 3 can be provided with both a connector needle (not

WO 2010/072664 PCT/EP2009/067490 8

shown as it is placed behind the bubble shaped membrane 17) and a bubble shaped self closing membrane 17 and the reservoir 6 can be provided with a bubble shaped self closing membrane. Hereby a fluid path is established providing transfer of medication e.g. insulin or nutrients from the reservoir to the connector part 3. As both parts are provided with self closing membranes it will be possible to separate the two units from each other and rejoin them at a later time without the connection part 3 and thereby the patient being contaminated.

10 Figs. 2A-G show embodiments of a medical device according to the invention having an approximately rectangular contact surface embodiment attached to an adhesive pad. The adhesive pad 2 of fig. 2A-G and the illustrated attachments can e.g. be used together with a surface plate 1 and a delivery device of the type shown in fig. 1A-C.

15

5

The base part shown in fig. 2A-D is a second embodiment differing from the embodiment shown in fig. 1A-C in that e.g. the guiding means 4 of the surface plate 1 comprises two elongated bars placed along opposite sides of the base part.

20

25

30

35

As described for the known embodiment of fig. 1 the surface plate 1 has a contact surface which is defined as the surface which is in contact with the the first surface of the adhesive pad 2 which is the surface of the adhesive pad 2 facing the surface plate 1. The contact surface of the surface plate 1 and the first side of the adhesive pad 2 has areas unreleasably secured to each other by welding. Further the second surface of the adhesive pad 2 i.e. the surface facing the skin of the patient has areas provided with a skin compatible adhesive. Normally the full surface of the second surface of the adhesive pad 2 will be adhesive except for the areas which have been subjected to welding when joining the surface plate 1 and the adhesive pad 2 together as welding ruins the adhesive surface opposite the welded surfaces.

Fig. 2A-2D shows an embodiment of a base part to which it is possible to join a delivery device; the base part comprises a surface plate 1 and an adhesive part 2.

Fig. 2A shows the surface plate 1 separated from the adhesive pad 2 although the two parts will be joined together by welding during manufacturing. The welding positions 32 are shown on the surface plate 1 and can be seen in fig. 2B, 2C and 2D where the surface plate 1 is seen from below. A first welding position is placed around the opening 12B through which the cannula part 7 enters. The welding is placed in a minimum distance from the cannula opening 12B in order assure that the welding will not ruin the ability of the adhesion pad 2 to adhere to the patients skin close to the opening 12B. The distance between the edge of the opening 12B and the edge of the welding 32 should be at least 2 mm, preferably at least 3 mm, i.e. leaving at least 2 mm, preferably at least 3 mm, of unspoiled adhesive surface on the second surface of the adhesive pad 2 but generally the adhesion between to given materials such as skin and skin compatible adhesive will be improved if the common adhesive surface is large i.e. the larger the better.

15

20

25

30

35

10

5

Further, the surface plate 1 has a welding position 32 close to the opposite end of the surface plate 1. This welding position 32 is shaped as a mouth or a crescent moon. The function of this rather large welding is to assure that the surface plate 1 will not pivot around the welding and/or other fastening means positioned at the opposite end i.e. the "cannula" end, but will be firmly positioned relative to the adhesive pad 2.

The reference numbers of fig. 2A refers to similar parts with same numbers as described in fig. 1A-1C, "similar parts" are parts with same function although not with exactly the same look.

The surface plate 1 of this embodiment is rather large and rigid. That the surface plate is large means that it has a dimension which is more than 3 cm long e.g. the diameter should be at least 3 cm for a round surface plate 1, when the surface plate 1 has credit card size it has a length of at least 8 cm and a width of at least 4 cm, the adhesive pad 2 will be larger than the contact surface of the surface plate, normally the adhesive pad 2 will extend the contact surface with at least 3 mm in all directions i.e. if the contact surface is round and have a diameter of 4 cm the diameter of a round adhesive pad 2 would be at least 4.6 cm and the length/width of a square adhesion pad 2 would be at least 4.6 cm.

5

10

15

20

25

30

35

The adhesive pad 2 of fig. 2A-B is provided with a release liner 31; a release liner protects the adhesive surface before use but can easily be peeled of by the user before the base part is to be positioned on the patient's skin. In fig. 2A which shows the embodiment from above it is only possible to see a handle part of the two-piece release liner 31. Also the embodiment of the base part shown in fig. 2A is provided with an adhesive part 30 which is shown as secured to the adhesive pad 2. The adhesive part 30 can be a double coated tape. If the adhesive part 30 is placed close to the edge of the adhesive pad 2 which is normally less than 1 mm thick then it would be suitable to apply a tape approved for medial use such as e.g. the tape of type 1517 from 3M. If the adhesive part 30 is placed away from the edge of the adhesive pad 2 it is not important to use a tape approved for medical use as the patient is adequately separated from the tape. But in both cases it should be possible to sterilize the tape or coating as the whole medical device will have to be sterilized before use. Normally gamma radiation or ethylene gas is used to sterilize medical devices, while this makes it desirable that the tape or coating should be able to withstand such sterilization and be able to sustain a sufficient adhesion afterwards. Adhesive parts 30 in the form of medical grade pressure sensitive plastic, non-woven and foam adhesive tapes which are suitable for the present use can be bought commercially.

The adhesive part 30 of the embodiment in fig. 2A-2D is rectangular and has a T-shaped opening which closely follows the edge of the opening 12B in order to keep the surface plate 1 as firmly positioned in this area as possible.

The surface plate 1 of the embodiment in fig. 2A-D is not provided with a cannula or another subcutaneous part but the base part is provided with an opening 12A / 12B which can receive a cannula or another subcutaneous part 7 and when the medical device is in use the cannula or another subcutaneous part will be positioned in this opening 12A/B.

Figs. 2E-2G illustrate the use of spot welding when replacing larger continued weldings such as those weldings illustrated in figs. 2A-2D. The spot weldings can have the form of small circles or short lines. That the circle is small means that no adhesive effect between skin and pad 2 is achieved within the

circle, and that a line is short means that if it was rounded to a circle, i.e. tight

11

PCT/EP2009/067490

WO 2010/072664

15

20

25

30

35

circle, and that a line is short means that if it was rounded to a circle, i.e. tight together at the ends, no adhesive effect between skin and pad would be achieved within the formed circle.

In fig. 2E the adhesive pad 2 and the contact surface is provided with two circular spot weldings 32 i.e. one on each side of the opening 12B through which the subcutaneous device passes. The opening 12B is placed close to the edge of the surface plate 1 and an adhesive part 30 is placed around the opening 12B. Further the adhesive pad 2 and the contact surface is provided with two circular spot weldings 32 at the opposite end, i.e. one at each side of the contact surface in order to prevent the surface plate 1 to separate from the adhesive pad 2 and pivot away from the patients skin.

In fig. 2F the adhesive pad 2 and the contact surface is provided with linear spot weldings 32 i.e. one on each side of the opening 12B through which the subcutaneous device passes. Like in fig. 2E an adhesive part 30 is placed around the opening 12B.Further the adhesive pad 2 and the contact surface is provided with two linear spot weldings 32 at the opposite end, i.e. one at each side of the contact surface in order to prevent the surface plate 1 to separate from the adhesive pad 2 and pivot away from the patients skin.

In fig. 2G the adhesive pad 2 and the contact surface is provided with two circular spot weldings 32 i.e. one on each side of the opening 12B through which the subcutaneous device passes. The opening 12B is placed around the middle of the surface plate 1 and an adhesive part 30 is placed around the opening 12B. Further the adhesive pad 2 and the contact surface is provided with two linear spot weldings 32 at each end of the surface plate 1, i.e. one at each side of the contact surface in order to prevent the surface plate 1 to separate from the adhesive pad 2 and pivot away from the patients skin at either end.

Fig. 3A and 3B illustrates how the invention can be applied when dealing with a smaller medical device i.e. a medical device which has a contact surface smaller than 3 cm in all dimensions parallel to the skin of the patient. The shown embodiments of the adhesive pads 2 are both round having a central

opening 12B which makes it possible to insert a subcutaneous part through the adhesive pad 2.

Fig. 3A illustrates an embodiment of the prior art where welding positions 32 (illustrated by 8 fat lines) often are positioned as rays extending from the center to the perimeter at the area between the contact surface of the surface plate 1 and the first surface of the adhesive pad 2. This embodiment assures a very firm attachment between the adhesive pad 2 and the surface plate 1.

5

Fig. 3B illustrates an embodiment according to the invention where welding positions 32 (illustrated by 4 fat lines) will placed along the edge of the contact surface of the surface plate 1 when the surface plate 1 has been secured to the adhesive pad 2. It is obvious that this embodiment will provide a much large area of adhesion between the adhesive pad 2 and the patient's skin as a smaller area of the adhesive surface will be destroyed by welding. The central opening 12B is surrounded by an adhesive part 30 which will provide adequate adhesion between the surface plate 1 and the adhesive pad 2 despite the smaller welded area.

#### **Claims**

10

15

20

25

- 1. A medical device comprising
  - a cannula (22) or another part to be positioned subcutaneously when in use,
- a surface plate (1) provided with a contact surface and with an opening (12B) through which the cannula (22) or another subcutaneously positioned part passes when the medical device is in use, and
  - an adhesive pad (2) secured to the contact surface of the surface plate (1) providing adhesion of the surface plate (1) to a skin surface which adhesive pad (2) comprises
    - a first surface facing the contact surface and having areas unreleasably secured to the contact surface by welding, and
  - a second surface facing the skin of a patient during use and having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient,
  - characterized in that an adhesive part (30) has been placed between the contact surface of the surface plate (1) and the first surface of the adhesive pad (2) in an area where the two surfaces have not been welded together thereby securing these unwelded areas of the contact surface to the first surface.
  - 2. A medical device according to claim 1, wherein the adhesive part (30) comprises a piece of double adhesive material i.e. each side of the adhesive part (30) is provided with adhesive coating or the adhesive part (30) comprises a coating of adhesive placed directly on the contact surface of the surface plate (1) or the adhesive part (30) comprises a coating of adhesive placed directly on the first surface of the adhesive pad (2).
- 3. A medical device according to claim 1 or 2, wherein an adhesive part (30) is positioned along the edge of the opening (12B) of the contact surface of the surface plate (1) through which opening (12B) the cannula (22) or another subcutaneously positioned part passes.
- 4. A medical device according to claim 1, 2 or 3, wherein the adhesive part(30) comprises a piece of double adhesive tape which can be sterilized by either gamma radiation or ethylene oxide gas.

- 5. A medical device according to claim 3 or 4, wherein the area covered by the adhesive part (30) is between  $0.5 1.5 \text{ cm}^2$ .
- 5 6. A medical device according to any of the claims 1-5, wherein weldings in the form spot weldings are placed on at least two opposite sides of the adhesive part (30).
- 7. A medical device according to any of the claims 1-6, wherein a welding is also placed between the adhesive part (30) and at least one edge of the surface plate 1.
  - 8. A medical device according to claim 7, wherein the welding placed between the adhesive part (30) and at least one edge of the surface plate 1 comprises either a larger circular welding or one or more spot weldings.
  - 9. A medical device according to any of the claims 1-8, wherein the subcutaneously positioned part is a sensor.

# 20 10. A base part

15

25

30

35

- a surface plate (1) provided a contact surface and with an opening (12B) through which a cannula (22) or another subcutaneously positioned part passes when the medical device is in use, and
- an adhesive pad (2) secured to the contact surface of the surface plate (1) providing adhesion of the surface plate (1) to a skin surface which adhesive pad comprises
  - a first surface facing the contact surface and having areas unreleasably secured to the contact surface by welding, and
- a second surface facing the skin of a patient during use and having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient,

characterized in that an adhesive part (30) has been placed between the contact surface of the surface plate (1) and the first surface of the adhesive pad (2) in an area where the two surfaces has not been welded together thereby optimizing the adherence between these unwelded areas of the contact surface to the first surface.

- 11. An adhesive pad secured to a medical device and providing adhesion of the medical device to a skin surface which adhesive pad comprises
  - a first surface facing the medical device having areas unreleasably secured to the medical device by welding, and

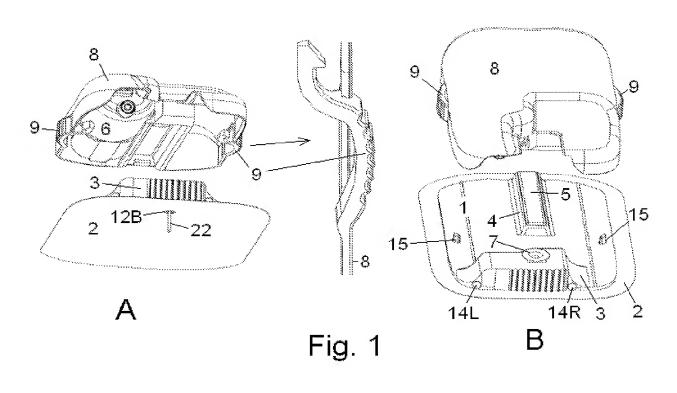
5

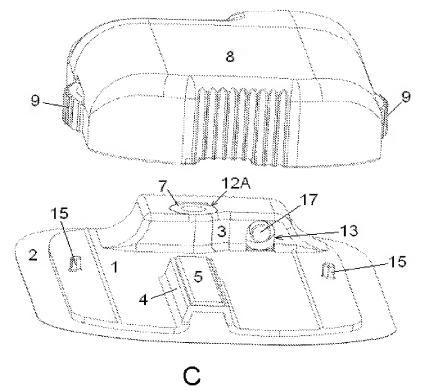
10

15

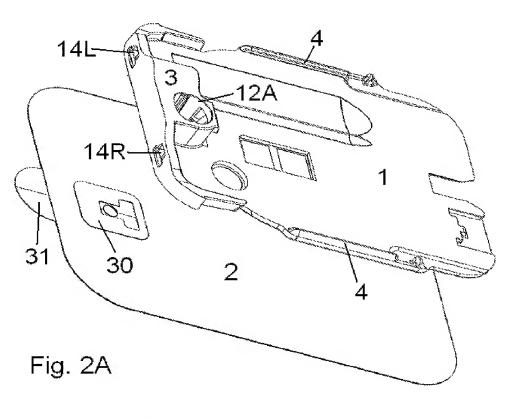
- a second surface having areas provided with a skin compatible adhesive which can be releasably secured to the skin of a patient,
- characterized in that the first surface has at least one area provided with an adhesive securing the first surface to the medical device.

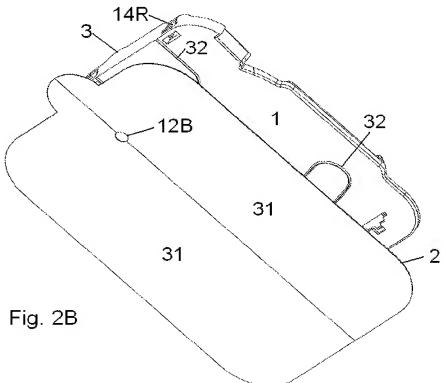
12. An adhesive pad according to claim 11, wherein the medical device is provided with a cannula (22) and that the at least one area provided with an adhesive is surrounding the point where the cannula pass through the adhesive pad (2).

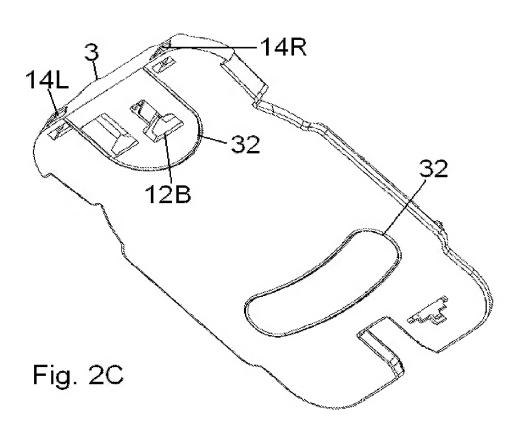


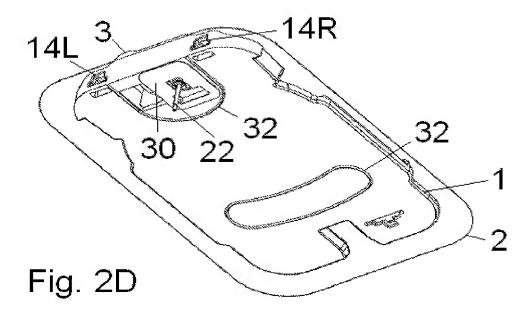


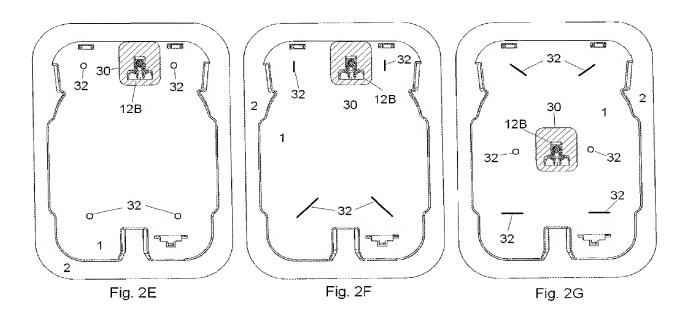


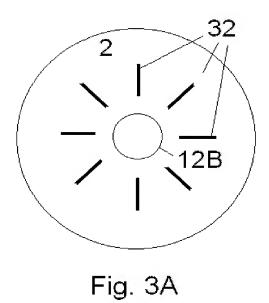












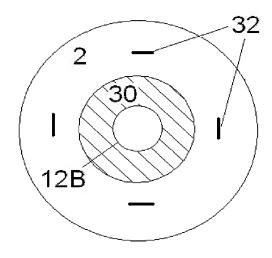


Fig. 3B

# INTERNATIONAL SEARCH REPORT

International application No PCT/EP2009/067490

A. CLASSI INV.	FICATION OF SUBJECT MATTER A61M25/02 A61M5/158								
According to International Patent Classification (IPC) or to both national classification and IPC									
B. FIELDS SEARCHED									
Minimum documentation searched (classification system followed by classification symbols) A61M									
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched									
Electronic d	lata base consulted during the international search (name of data bas	se and, where practical, search terms used	)						
EPO-In	ternal								
C. DOCUMENTS CONSIDERED TO BE RELEVANT									
Category*	Citation of document, with indication, where appropriate, of the rele	Relevant to claim No.							
A	GB 2 423 267 A (FOCUS PRODUCT DEV LTD [GB]) 23 August 2006 (2006-08 the whole document	1–12							
А	EP 1 719 537 A (UNOMEDICAL AS [DK 8 November 2006 (2006-11-08) paragraphs [0009] - [0011], [001 [0022]; figures 1-4	1-5, 10-12							
		·							
Further documents are listed in the continuation of Box C.  X See patent family annex.									
* Special categories of cited documents:  "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the									
considered to be of particular relevance invention  "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention									
filing o	date ent which may throw doubts on priority claim(s) or	cannot be considered novel or cannot involve an inventive step when the doc	be considered to						
which is cited to establish the publication date of another citation or other special reason (as specified)  "Y" document of particular relevance; the claimed invention cannot be considered to involve an invention the considered to involve an invention cannot be considered to invention cann									
"O" document referring to an oral disclosure, use, exhibition or other means cannot be considered to involve a rind with one or more other such document is combined with one or more other such document such combination being obvious to a person skilled									
"P" docume	ent published prior to the international filing date but	in the art.  "8" document member of the same patent to	·						
Date of the	actual completion of the international search	Date of mailing of the international search report							
24 March 2010		01/04/2010							
Name and r	mailing address of the ISA/	Authorized officer							
	European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040,	Clarica Business							
Fax: (+31-70) 340-2040, Fax: (+31-70) 340-3016		Steiner, Bronwen							

# INTERNATIONAL SEARCH REPORT

International application No

	Information on patent family members				International application No PCT/EP2009/067490	
Patent document cited in search report		Publication date		Patent family member(s)	/	Publication date
GB 2423267	Α	23-08-2006	NONE			
EP 1719537	Α	08-11-2006	NONE			